EUROPEAN COMMISSION

Brussels, 5.5.2010
C(2010)3077

COMMISSION DECISION

of 5.5.2010

on the renewal of the marketing authorisation for the medicinal product for human use "PegIntron - Peginterferon alfa-2b", granted by Decision C(2000)1407

(ONLY THE FRENCH AND DUTCH TEXTS ARE AUTHENTIC)

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1], and in particular Article 10(2) thereof,

Having regard to the application submitted by Schering Plough Europe, on 26 October 2009, under Article 14(2) of Regulation (EC) No 726/2004 with a view to the renewal of the marketing authorisation for the medicinal product "PegIntron - Peginterferon alfa-2b"

Having regard to the opinion of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 18 February 2010,

Whereas:

(1) On the basis of a re-evaluation by the Agency of the risk-benefit balance following the consideration of a consolidated file, it appears that the medicinal product "PegIntron - Peginterferon alfa-2b", entered in the Community register of medicinal products under number(s) EU/1/00/131/001-050 and authorised by Commission Decision C(2000)1407 of 25 May 2000, complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[2].

(2) The marketing authorisation which expires on 5 June 2010 should therefore be renewed.

(3) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

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1 OJ L 136, 30.4.2004, p. 1.

2 OJ L 311, 28.11.2001, p. 67.

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation granted by Decision C(2000)1407 of 25 May 2000 which expires on 5 June 2010 is renewed.

Article 2

Decision C(2000)1407 is amended as follows:

1) Annex I is replaced by the text set out in Annex I to this Decision;

2) Annex II is replaced by the text set out in Annex II to this Decision;

3) Annex III is replaced by the text set out in Annex III to this Decision.

Article 3

This Decision is addressed to Schering Plough Europe, Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België.

Done at Brussels, 5.5.2010.

For the Commission
Paola TESTORI COGGI
Director-General